UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ACTION ALLIANCE OF SENIOR CITIZENS OF GREATER PHILADELPHIA, a Non-profit Philadelphia corporation, Individually and on behalf of all Others similarly situated,	:	IN RE NAPRELAN ANTITRUST LITIGATION
Plaintiff,	:	No. 02-cv-2095
v.	:	CLASS ACTION COMPLAINT
ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC	:	JURY TRIAL DEMANDED
Defendants.	:	

JEANINE MICHELLE WEBER, Individually and on behalf of all Others similarly situated,	:	
Plaintiff,	:	
v.	:	
ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC.,	:	
Defendants.	:	

CHARLES D. FREDERICKS, JR., On behalf of himself and all Others Similarly Situated,	:
Plaintiff,	:
v.	:
ELAN CORPORATION, PLC and SKYEPHARMA, INC. f/k/a BRIGHTSTONE PHARMA, INC.,	:
Defendants.	:

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

1. Plaintiffs, by their attorneys, upon personal knowledge as to facts pertaining to themselves, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

2. Naprelan® ("Naprelan") is the brand name of the controlled-release naproxen drug manufactured and marketed by defendant Elan Corporation, PLC ("Elan"). Naprelan is an analgesic used to treat, *inter alia*, rheumatoid arthritis, tendonitis, bursitis, and acute gout. Unlike over-the-counter formulations of naproxen, Naprelan maintains a consistent level of naproxen in the body when taken only once per day, thereby avoiding the undesirable fluctuations in naproxen concentrations in a patient's blood that can occur with multiple daily doses of

immediate-release naproxen. For many patients, controlled-release naproxen is uniquely suited to provide safe and effective pain relief, and sales of Naprelan in the United States amounted to approximately $55 million in 1999 alone.

3. No generic bioequivalent of Naprelan is currently marketed in the United States. The reason for this is simple. Defendant Elan has unlawfully monopolized and attempted to monopolize the market for controlled-release naproxen by filing several sham patent infringement lawsuits against potential generic competitors, and by conspiring with one of those potential generic competitors, Skyepharma, Inc., f/k/a Brightstone Pharma, Inc., ("Skyepharma"), to settle the patent lawsuit with an agreement that Skyepharma will keep its generic controlled-release naproxen (and in turn all other generic controlled-release naproxen products) off of the market, in exchange for a share of Elan's monopoly profits.

4. With the filing of each baseless patent infringement lawsuit, Elan improperly extended statutory restraints on trade, thereby preventing public access to a safe, effective and low-cost generic controlled-release naproxen product. Elan and Skyepharma (collectively, "defendants") then allocated the controlled-release naproxen market between themselves indefinitely by stipulating that, in exchange for consideration, Skyepharma would not exercise its right to market a generic controlled-release naproxen, thereby preventing all other generic companies from reaching the market. As a result of defendants' agreement, no generic version of Naprelan is sold today. This is costing plaintiffs and the Class they seek to

represent millions of dollars in savings they would realize if a generic version of Naprelan were on the market.

5. This is a class action brought under the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, state antitrust statutes, and common law for injunctive relief, damages and disgorgement of defendants' unlawfully obtained profits from the sale of Naprelan.

6. In Count I of this Complaint, plaintiffs, on their own behalf and on behalf of all others similarly situated (the "Nationwide End-Payor Class"), bring this action for injunctive relief against Elan and Skyepharma alleging a combination, contract or conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

7. Count II of this Complaint is brought by plaintiffs seeking injunctive relief on their own behalf and on behalf of the Nationwide End-Payor Class alleging monopolization of, and an attempt to monopolize, the market for Naprelan and generic bioequivalents of Naprelan, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

8. Counts III is brought for damages and injunctive relief under the indirect purchaser antitrust statutes on behalf of a subclass of end-payors who purchased or paid for Naprelan in Arizona, Arkansas, California, District of Columbia, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin ("the Indirect Purchaser Sub-Class").

9. Count IV of this Complaint is brought on behalf of the Nationwide End Payor Class for restitution, disgorgement and a constructive trust for unjust enrichment by defendants.

JURISDICTION AND VENUE

10. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for damages, injunctive relief and the costs of suit, including reasonable attorneys' fees, for injuries to plaintiffs and members of plaintiffs' Class resulting from, *inter alia*, defendants' violations of the federal antitrust laws, particularly Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. § 1-2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 26. The Court has supplemental jurisdiction over the state antitrust and common law claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because defendants transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

INTERSTATE TRADE AND COMMERCE

12. During all or part of the relevant time period:

(a) Defendants manufactured and sold substantial amounts of Naprelan in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States;

(b) Defendants transmitted funds as well as contracts, bills, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Naprelan; and

(c) Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines as well as means of interstate and international travel.

13. The contract, combination or conspiracy in restraint of trade and illegal monopolization and attempt to monopolize the market for Naprelan and generic Naprelan, i.e., controlled-release naproxen, alleged here, have substantially affected interstate trade and commerce.

THE PARTIES

Plaintiffs

14. Plaintiff Action Alliance of Senior Citizens of Greater Philadelphia ("Alliance") is a non-profit corporation organized under the laws of the Commonwealth of Pennsylvania and is located in Philadelphia County, Pennsylvania. Alliance has standing to bring suit for injunctive relief on behalf of its members, one or more of which have purchased and/or paid for Naprelan during the class period defined below and who individually would have standing to sue in their own right. The interests at stake in this litigation are germane to the

Alliance's purpose, and neither the claims asserted nor the injunctive relief requested requires the participation of individual members in this lawsuit.

15. Plaintiff Jeanine Michelle Weber ("Weber"), is an individual residing in Burlington County, New Jersey. Weber purchased Naprelan during the Class period defined below.

16. Plaintiff Charles D. Fredericks, Jr. ("Fredericks"), is an individual who resides in Evanston, Illinois. Fredericks purchased Naprelan during the class period defined below.

Defendants

17. Upon information and belief, defendant Elan is a corporation organized and existing under the laws of Ireland, having its corporate offices and principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. It is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the world.

18. Upon information and belief, defendant Skyepharma is the United States subsidiary of Skyepharma, PLC, which has its principal place of business at 105 Piccadilly, W1V 9FN, London, United Kingdom. Skyepharma is a corporation organized and existing under the laws of California, and has its principal place of business at 10450 Science Center Drive, San Diego, California 92121. Skyepharma is engaged in the business of manufacturing and marketing pharmaceuticals, and was the first company to submit to the United States Food and Drug

Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking permission to market a generic bioequivalent to Naprelan.

Others

19. Andrx Pharmaceuticals, Inc. (Andrx") is a corporation organized and existing under the laws of Florida, and has its principal place of business at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida, 33314. Andrx is engaged in the business of manufacturing and marketing pharmaceuticals, and has applied to the FDA for permission to market a generic bioequivalent to Naprelan.

RELEVANT MARKETS

20. The relevant product market is the market for the manufacture and sale of Naprelan and a generic bioequivalent rated "AB" by the FDA. The relevant geographic market is the United States. At all relevant times, including the present, defendants' market share in the relevant product and geographic markets was 100%. By alleging these relevant markets, plaintiff and the Class do not waive any allegations asserting that defendants' conduct is a *per se* violation of the federal and state antitrust laws.

FACTUAL ALLEGATIONS

21. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. In 1997, over $97 billion of prescription drugs were dispensed in the United States alone. The sale of prescription drugs in the United States grew to $120 billion by 1999, and is estimated to have reached $132 billion in 2000.

A. The Federal Scheme For Approval Of Pioneer Drugs

22. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Premarket approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act").

23. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

24. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication entitled "Approved Drug

Products With Therapeutic Equivalence Evaluations." This publication is commonly referred to as the "Orange Book."

25. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

B. Generic Drugs Generally

26. Generic drugs are drugs that the FDA has found to have the same chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. A branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition, unless the branded manufacturer lowers prices to meet competition.

27. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then (a) for consumers covered by most insurance plans, the pharmacist will substitute

the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

28. Once a physician writes a prescription for a brand-name drug such as Naprelan, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug. As explained on one generic manufacturer's web page:

> The majority of states use the FDA's "AB" rating of therapeutic substitution as the foundation for generic substitution, either by permitted substitution based on the FDA's Orange Book listing, or by using the FDA's "AB" rating as the basis for cursory administrative approval. A total of 39 states permit substitution of generic products while 11 state mandate generic substitution.
>
> URL http://www.barrlabs.com/pages/faqcon.htm

29. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. As explained on the same web page:

> Generic pharmaceuticals cost less than the equivalent, branded product. Yet, the consumer is getting the same product, manufactured to the same high standards, as the brand name product.
>
> * * *
>
> [I]ntroduction of generic products – which offer consumers a choice – results in competition that can also help lower prices. The generic makes a real contribution to lowering health care costs, by offering the very same quality pharmaceutical products at significantly lower prices.
>
> URL http://www.barrlabs.com/pages/faqcon.htm

C. Abbreviated New Drug Application for Generic Drugs

30. Congress enacted the Hatch-Waxman Act in 1984 to expedite the approval of *generic* drugs. Consumers benefit from choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an ANDA, which incorporates by reference the safety and effectiveness data developed and previously submitted by the company that manufactured the original, "pioneer" drug. The Act also provides an economic incentive to the first manufacturer to file an ANDA for a generic version of a particular branded drug – a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its generic drug free from other generic competition.

31. The most important information that must be included in the ANDA concerns the generic company's position vis-à-vis the patent that the pioneer manufacturer claims applies to the drug. The ANDA filer must make one of four certifications:

(a) that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

(b) that the patent for the pioneer drug has expired (a "Paragraph II Certification");

(c) that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

(d) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification"). 21 U.S.C. § 355(j)2(A)(vii).

32. In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id*.

33. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(i). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. *See id*.; 21 C.F.R. § 314.95.

34. The branded drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(2)(B)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notices of the Paragraph IV Certification, or a final judicial determination of non-infringement.

35. Accordingly, pioneer drug patent holders need only to *file* a patent infringement lawsuit within 45 days of receipt of a Paragraph IV Certification in

order to *automatically* block an ANDA applicant's generic drug from entering the market for up to 30 months.

D. Elan's Unlawful Course of Conduct In Making Misrepresentations To The FDA and PTO, And Filing Serial Sham Litigation

1. Elan's Naprelan NDA and '320 Patent

36. On January 5, 1996, the FDA approved Elan's NDA No. 020353 (the "Naprelan NDA"), thereby clearing the way for Elan to market its controlled-release naproxen product.

37. Subsequently, on June 10, 1997, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,637,320, entitled "Controlled absorption naproxen formulation for once-daily administration" ("the '320 patent"). The '320 patent purportedly claimed several formulations of controlled-release naproxen, including the formulation marketed by Elan as Naprelan. Elan purportedly owns the '320 patent.

38. As recently confirmed by the United States District Court for the Southern District of Florida, the '320 patent is invalid because Elan offered the controlled-release naproxen product that is the subject of the '320 patent for sale more than one year before it filed the application for the '320 patent, in violation of 35 U.S.C. §102(b). *See Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.*, No. 98-CV-7164, Findings of Fact and Conclusions of Law at 1 (S.D.Fla. March 14, 2002).

39. The '320 patent is also invalid and unenforceable for either or both of the following reasons:

(a) The claims of the '320 patent were anticipated as and/or obvious in view of numerous prior art references, including but not limited to Elan's 1989 annual report and the patent for diltiazem, another Elan product; and/or

(b) Elan behaved inequitably in front of the PTO by fraudulently withholding material information from the patent examiner, including but not limited to the fact that the controlled-release formulation of naproxen tested in an article by *Kelly et al.* (Eur. J. Clin. Pharmacol. (1989) 36:383) was the same formulation of controlled-release naproxen that is recited in the '320 patent.

40. Although Elan knew that the '320 patent was invalid and unenforceable, Elan nonetheless submitted it to the FDA for listing with the Naprelan ANDA.

41. Pursuant to the Act, in its ministerial capacity, the FDA was improperly caused to list the '320 patent in connect with the Naprelan NDA in the Orange Book.

42. As of January 5, 1996, the date on which the FDA approved the Naprelan NDA, Elan began to enjoy a five-year statutory monopoly in the market for controlled-release naproxen by reason of he FDA's determination that the NDA contained a new, previously unapproved active ingredient. During that five-year period, the Act and applicable regulations barred the FDA from approving any ANDA that referenced the Naprelan NDA. However, that five-year period of exclusivity ended on January 5, 2001. In the absence of defendants' anticompetitive activity, then, beginning January 5, 2001, the FDA would have been free to end

Elan's temporary Naprelan monopoly by approving an ANDA that referenced the Naprelan NDA. 21 U.S.C. § 355(j)(5)(I)(ii).

2. Skyepharma's ANDA

43. Skyepharma submitted an ANDA to the FDA for a controlled-release naproxen product and, on information and belief, included the required studies demonstrating that its product is bioequivalent to the approved product.

44. Skyepharma addressed the only patent listed in connection with the Naprelan NDA – the '320 patent – with a Paragraph IV Certification, stating that the manufacture, sale, or use of Skyepharma's proposed controlled-release naproxen drug would not infringe such patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

45. Skyepharma was the first applicant to file an ANDA which referenced the Naprelan NDA and which contained a Paragraph IV Certification, thereby entitling it to market exclusivity on generic controlled-released naproxen for a 180-day period that would begin to run either when Skyepharma began commercial marketing of its controlled-release naproxen product, or when a court decided that the generic product did not infringe the patent subject to Paragraph IV Certification or that such patent is invalid or unenforceable. 21 U.S.C. §355(j)(5)(B)(iv).

3. Litigation Against Skyepharma

46. Skyepharma notified Elan of the filing of the ANDA and of the reasons why the manufacture, sale, or use of its controlled-release naproxen drug did not infringe Elan's '320 patent. 21 U.S.C. § 355(j)(2)(B)(i).

47. Skyepharma's Paragraph IV Certification on the '320 patent created the requisite subject matter jurisdiction to enable Elan to file an infringement action within 45 days after receiving notice of the Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. §271(e)(2).

48. On September 10, 1998, Elan sued Skyepharma (then known as Brightstone) in the United States District Court for the Eastern District of North Carolina (98-cv-701), for alleged infringement of the '320 patent, pursuant to U.S.C § 355(j)(5(B)(iii); U.S.C. § 271(e)(2).

49. When it filed that action, Elan knew that the '320 patent was not validly issued, that it was improperly listed by the FDA, and that Skyepharma's product did not infringe the '320 patent. Elan therefore knew that its suit was baseless.

50. Elan's lawsuit was intended to keep generic controlled-release naproxen off of the market. And it did, as the filing of the litigation extended Elan's monopoly beyond January 5, 2001, the date on which the FDA could otherwise have approved an ANDA for a generic version of Naprelan.

4. Litigation Against Andrx

51. Elan's sham litigation strategies have not been confined to Skyepharma.

52. Andrx filed with the FDA ANDA No. 75-416 for a controlled-release naproxen product and included the appropriate Paragraph IV Certification to the '320 patent.

53. Pursuant to section 505(j)(2)(B) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), Andrx notified Elan that the product for which Andrx sought approval does not infringe on the '320 patent.

54. Despite its knowledge that Andrx's controlled-release naproxen does not infringe on the '320 patent, on October 23, 1998, Elan filed suit against Andrx in the Southern District of Florida (98-cv-7164)(the "First Florida Action"), claiming infringement of the '320 patent. When it filed the First Florida action, Elan knew that the '320 patent was not validly issued, that it was improperly listed by the FDA, and that Andrx's product did not infringe the '320 patent. Elan therefore knew that its suit was baseless.

55. The First Florida Action was and is baseless, and intended to block Andrx from selling its generic after Elan's five-year exclusivity period ended.

56. Andrx later sought permission from the FDA to market a different dosage form of its controlled-release naproxen product, and made a Paragraph IV Certification to the '320 patent for that dosage form.

57. Despite its knowledge that the new dosage form of Andrx's controlled-release naproxen did not infringe on the '320 patent, on July 26, 2000, Elan filed patent litigation against Andrx in the Southern District of Florida (00-cv-7057) (the "Second Florida Action"), claiming infringement of the '320 patent. When it filed the Second Florida action, Elan knew that the '320 patent was not validly issued, that it was improperly listed by the FDA, and that Andrx's product did not infringe the '320 patent. Elan therefore knew that its suit was baseless.

58. The Second Florida Action was and is baseless, and intended to block Andrx from selling its generic for at least 30 months.

59. On March 14, 2002, the Southern District of Florida held that the '320 patent was invalid – a victory for Andrx. See *Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.,* No. 98-CV-7164, 2002 U.S. Dist. LEXIS 4457 (S.D. Fla. March 14, 2002). This decision cleared the way for the eventual marketing of Andrx's generic Naprelan. Andrx recently announced it has obtained a waiver from the FDA of the first to file limitation and that it intends to begin marketing 500-mg versions of Naprelan beginning this September. This has not yet happened. Andrx has also said that it cannot market the 375 mg version. Thus, to date, no generic versions of Naprelan are on the market.

60. As a result, Elan has and will continue to improperly maintain its monopoly over the market for Naprelan and generic bioequivalents of Naprelan.

5. Agreement Between Elan and Skyepharma

61. On May 13, 1999, Elan and Skyepharma entered into an agreement (the "Agreement") "settling" the patent infringement litigation between them.

62. Elan acknowledges the existence of the Agreement, which is subject to discovery in the Florida patent infringement actions against Andrx. However, Elan has refused to produce the Agreement during the course of litigation with Andrx, and refuses to disclose its terms.

63. The Agreement has prevented Skyepharma, the first generic manufacturer to file an ANDA, from marketing its product. Upon information and

belief, the terms of the Agreement provide for the payment of valuable consideration to Skyepharma for "admitting" that its generic infringes the '320 patent, obtaining from Elan a license to market its generic, and finally, refraining from actually bringing its generic to market. Because Skyepharma was the first company to submit an ANDA to the FDA seeking permission to market a generic version of Naprelan, it is entitled to the 180-period of market exclusivity. Skyepharma's failure to bring its product to market, pursuant to its Agreement with Elan, prevents the exclusivity period from running, and has the purpose and effect of blocking other generic versions of Naprelan (including Andrx's product) from reaching the market. Moreover, at the time it settled the lawsuit, Skyepharma knew that the pending patent litigation was baseless.

CLASS ACTION ALLEGATIONS

64. Plaintiffs bring this action on their own behalf and under Rule 23(b)(2)(b) of the Federal Rules of Civil Procedure, with respect to the declaratory and equitable relief sought herein, and Rule 23(b)(3) with respect to the damages sought herein, as representatives of the Class, defined as follows:

> With respect to Counts I, II and IV, all persons or entities throughout the United States and its territories who purchased and/or paid for Naprelan, for consumer use and not for resale, at any time during the period from January 5, 2001, to the present (the "Class Period")(The "National End Payor Class").
>
> With respect to Counts II and III, a sub-class consisting of all persons or entities who purchased and/or paid for Naprelan in the "indirect purchaser states" for personal use at any time during the period from January 5, 2001 to the present (the "Indirect Purchaser Sub-Class").

Excluded from the Sub-Class are all governmental entities and the defendants and their respective subsidiaries and affiliates. Collectively, the National End Payor class and Indirect Purchaser Sub-Class are referred to as the "Class".

65. More than a million Americans have purchased Naprelan. Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and records maintained by pharmacies, drugstores and managed care organizations.

66. Plaintiffs' claims are typical of the members of the Class, in that plaintiffs purchased and/or paid for Naprelan during the Class Period. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of the defendants.

67. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

68. In addition, plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

69. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because defendants have acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole. Such conduct

is defendant Elan's exclusionary and anticompetitive efforts to defraud the FDA and PTO, its filing of serial sham litigation for the sole purpose of monopolizing and attempting to monopolize the market for Naprelan and generic bioequivalents of Naprelan, as hereinabove alleged, as well as defendant Elan's and defendant Skyepharma's collusion in "settling" their patent dispute in an anticompetitive manner.

70. Questions of law and fact common to the Class include:

a) Whether defendants engaged in a combination, contract or conspiracy to allocate the market for Naprelan;

b) The duration and extent of the alleged combination, contract or conspiracy;

c) Whether the alleged combination, contract or conspiracy violates Section 1 of the Sherman Act;

d) The effect of the alleged combination, contact or conspiracy upon the price of Naprelan;

e) Whether Elan monopolized or attempted to monopolize the market for Naprelan;

f) Whether defendant intentionally and unlawfully excluded competitors from the market;

g) Whether the alleged monopoly or attempted monopoly violates Section 2 of the Sherman Act;

h) How to properly define the relevant geographic and product markets;

i) Whether defendants' conduct is subject to *per se* treatment under the antitrust laws; and if not whether any procompetitive justifications exist for the allegedly illegally restraint of trade;

j) Whether defendants were unjustly enriched at the expense of plaintiffs; and,

k) Whether plaintiffs are entitled to equitable or injunctive relief?

71. The common questions as to whether defendants violated the Sherman Act are the same for the state antitrust claims. Each of the indirect purchaser state antitrust statutes have the same essential elements as federal claims for violations of Sections 1 and 2 of the Sherman Act. In fact, in interpreting equivalent state antitrust statutes, courts either follow federal Sherman Act precedent, find federal case law persuasive, or both.

72. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

73. Plaintiffs know of no difficulty to be encountered in litigation of this action that would preclude its maintenance as a class action.

COUNT I

Injunctive Relief for Violation of 15 U.S.C. § 1 (On Behalf of the Nationwide End-Payor Class)

74. Plaintiffs incorporate by reference the preceding allegations.

75. Beginning on or about May 13, 1999, defendants engaged in a continuing agreement, combination or conspiracy in unreasonable restraint of trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

76. Defendants' contract, combination or conspiracy has included concerted actions and undertakings between defendants with the purpose and effect of (a) allocating the market for sales of Naprelan and generic versions of Naprelan in the U.S. to Elan and Skyepharma; (b) allocating a portion of Elan's now-illegal monopoly profits to Skyepharma; (c) fixing, raising, maintaining and stabilizing the price of Naprelan; and (d) depriving plaintiffs and the Class of the opportunity to purchase a generic alternative to Naprelan.

77. Plaintiffs and other members of the Class seeking injunctive relief to prevent injury in their business or property by reason of defendants' antitrust violations as alleged in this Count. Their injury consists of paying higher prices for controlled-release naproxen than they would have paid in the absence of defendants' violations. Their injury is of the type the antitrust laws were designed to prevent and flows from that which makes defendants' conduct unlawful.

COUNT II

Injunctive Relief for Violation of 15 U.S.C. § 2
(On Behalf of the Nationwide End-Payor Class)

78. Plaintiffs incorporate by reference the preceding allegations.

79. Pursuant to the Federal Food, Drug, and Cosmetic Action 21 U.S.C. § 301 *et seq*., Elan was given a lawful monopoly over sale of Naprelan prior to January 5, 2001.

80. As described above, Elan knowingly and willfully engaged in a course of conduct designed to extend its monopoly power beyond the boundaries of the law. This course of conduct included, *inter alia*: (a) the submission of false patent information to the FDA; (b) the submission of fraudulent statements to and omissions of material facts from the PTO; and (c) the repeated prosecution of baseless, sham patent suits against its potential generic competitors. The result of Elan's unlawful conduct has been to extend Elan's monopoly beyond the time period permitted by law.

81. As described above, Skyepharma knowingly and willfully engaged in a course of conduct designed to perpetuate Elan's monopoly power beyond the boundaries of the law, and to share in that monopoly power. This conduct included entering into the Agreement to "settle" the infringement suit against it in a manner that prevented generic versions of Naprelan from reaching the market.

82. During the time periods describe above, Elan and Skyepharma have intentionally and wrongfully attempted to maintain and maintained monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III

Compensatory, Multiple Damages and Injunctive Relief Under the Antitrust Statutes of the Indirect Purchase States (On Behalf of the Indirect Purchaser Sub-Class)

83. Plaintiffs incorporate by reference the preceding allegations.

84. Defendants' conduct constitutes an illegal agreement, combination, or conspiracy, unreasonable restraint of trade and commerce and unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct of the antitrust laws of the indirect purchasers states as follows:

(a) Arizona: The aforementioned practices by defendants were and are in violation of Arizona Revised Statutes §§ 44-140, *et seq*.;

(b) Arkansas: The aforementioned practices by defendants were and are in violation of the Ark. Stat. Ann. § 4-88-101 *et seq*.;

(c) California: The aforementioned practices by defendants were and are in violation of the Cartwright Act, California Business and Professions Code §§ 16700, *et seq*.;

(d) District of Columbia: The aforementioned practices by defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq*.;

(e) Iowa: The aforementioned practices by defendants were and are in violation of the standard set forth by the Iowa Supreme Court in *Comes v. Microsoft* 2002 Iowa Sup. LEXIS 123 (June 12, 2002);

(f) Kansas: The aforementioned practices by defendants were and are in violation of the Kansas Unfair Trade and Consumer Protection Act, Kan. Stat. Ann. §§ 50-101, *et seq*.;

(g) Maine: The aforementioned practices by defendants were and are in violation of the Maine Trade Regulation Law of 1954, 10 M.R.P.S.A. §§ 1101, *et seq*.;

(h) Massachusetts: The aforementioned practices by defendants were and are in violation of the Massachusetts Consumer Protection Act, M.G.L. Ch. 93A, *et seq.;*

(i) Michigan: The aforementioned practices by defendants were and are in violation of the Michigan Antitrust Reform Act, MCL §§ 445.771, *et. seq.;*

(j) Minnesota: The aforementioned practices by defendants were and are in violation of the Minnesota Antitrust Act of 1971, MINN. STAT. §§ 325D.49, *et seq.;*

(k) Mississippi: The aforementioned practices by defendants were and are in violation of the Miss. Code Ann. § 75-21-9, *et seq.;*

(l) Nebraska: The aforementioned practices by defendants were and are in violation of the Neb. 59-801, *et seq*.;

(m) Nevada: The aforementioned practices by defendants were and are in violation of the NRS 598A.210, *et seq*.;

(n) New Mexico: The aforementioned practices by defendants were and are in violation of the New Mexico Anti-Trust Act, N.M. Stat. Ann. §§ 57-1-1, *et. seq.;*

(o) New York: The aforementioned practices by defendants were and are in violation of the New York Donnelly Act, GBL §§ 340, *et seq.;*

(p) North Carolina: The aforementioned practices by defendants were and are in violation of the North Carolina's Antitrust Law, N.C. G.S. §§ 75-1, *et. seq.;*

(q) North Dakota: The aforementioned practices by defendants were and are in violation of North Dakota's Antitrust Law, North Dakota Cent. Code §§ 51-08.101, *et seq.;*

(r) South Dakota: The aforementioned practices by defendants were and are in violation of South Dakota's Antitrust Law, S.D. Codified Law Ann. 37-1, *et seq.;*

(s) Vermont: The aforementioned practices by defendants were and are in violation of 9 Vt. Stat. Ann. 2465, *et seq.;*

(t) Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et. seq.;*

85. As a result of the conduct described above, plaintiffs and the Indirect Purchaser Sub-Class have sustained and will continue to sustain substantial losses and damage through the businesses and property in the form of, *inter alia*, paying prices for Naprelan that were higher than what they would have been, but for defendants' improper actions. The full amounts of such damages are presently unknown and will be determined after discovery and upon proof at trial.

86. Plaintiffs and the Indirect Purchaser Sub-Class seek damages and multiple damages, as permitted by law, for their injuries caused by these violations pursuant to these statutes.

COUNT IV

For Restitution, Disgorgement, and Constructive Trust for Unjust Enrichment by Defendants (On Behalf of the Nationwide End-Payor Class)

87. Plaintiffs incorporate by reference the preceding allegations.

88. As a result of defendants' unlawful conduct described above, defendants have been and will continue to be unjustly enriched. Specifically, defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and illegal monopoly profits on their sale of Naprelan.

89. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for Naprelan made by plaintiffs and the Nationwide End-Payor Class.

90. Plaintiffs and the members of the Nationwide End-Payor Class are entitled to the amount of defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct. Plaintiff and the Nationwide End-Payor Class members may make claims on a *pro-rata* basis for restitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3)

of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring plaintiffs as representatives of the Class and their counsel for the Class;

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful violations of Sections 1 and 2 of the Sherman Act, the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment; and,

C. Plaintiffs and each member of the Class recover the amounts by which defendants have been unjustly enriched;

D. Defendants be enjoined from continuing the illegal activities alleged herein;

E. Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

F. Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as maybe determined to be just, equitable, and proper by this Court.

JURY DEMAND

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues triable.

Dated: _____

Respectfully submitted,

_____

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